Exhibit A

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October 17, 2006

John T. Montgomery
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BY FEDERAL EXPRESS

Sandra K. Evans
Acting Deputy Director
Office of Administration
725 17th Street, NW
Washington, DC 20503

Victor Bernson, Esq.
General Counsel
Office of Administration
725 17th Street, NW
Washington, DC 20503

Re: *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, D. Mass. Civil Action No. 01-12257-PBS, Judge Patti B. Saris

Dear Ms. Evans and Mr. Bernson:

I write on behalf of Track 1 Defendants ("Defendants") in the above-referenced litigation regarding our intent to request the testimony of Christopher C. Jennings, former Deputy Assistant to the President for Health Policy Development, at a trial in the United States District of Massachusetts beginning on November 6, 2006. The trial concerns the so-called Average Wholesale Price for drugs reimbursed under Medicare Part B, and will proceed before Judge Patti B. Saris.

As an initial matter, we believe that the relevant *Touhy* regulation – 5 C.F.R. § 2502.30 *et. seq.* – is inapplicable because the United States is a party to the above-referenced action.[1] The Justice Department has informed Defendants that it disagrees with this position.[2] While we

[1] Federal courts are virtually unanimous that "the Supreme Court's holding in *Touhy* is applicable only in cases where the United States is not a party to the original legal proceeding." *Alexander v. F.B.I.*, 186 F.R.D. 66, 70 (D.D.C. 1998); *see also State of Louisiana v. Sparks*, 978 F.2d 226, 234 (5th Cir.1992); *Boron Oil Co. v. Downie*, 873 F.2d 67, 70 (4th Cir. 1989). That is, "in cases originating in federal court in which the federal government is a party to the underlying litigation, the *Touhy* problem simply does not arise." *Alexander*, 186 F.R.D. at 70. This is because "where the United States is a party to litigation, 'judicial control over the evidence in a case cannot be abdicated to the caprice of executive officers.'" *Id.* (citing *United States v. Reynolds*, 345 U.S. 1, 9-10 (1953)).

[2] In prior correspondence regarding potential testimony from former employees of the Department of Health and Human Services, Defendants expressed their position to counsel for the United States in this action. (*See* Ltr. from John T. Montgomery to Gejaa T. Gobena and George B. Henderson, II (Aug. 31, 2006), attached hereto as Ex. 1.) The Justice Department insisted that the United States is not a party to the case (*see* Ltr. from George B. Henderson, II (Sept. 12, 2006), attached hereto as Ex. 2), notwithstanding the fact that the Government appears as a

reserve our right to contest the Government's position, we are notifying you in order to avoid an unnecessary dispute. However, given that the trial is less than a month away, we respectfully ask that you inform us of your decision by October 24, 2006.

5 C.F.R. § 2502.31 provides that "[n]o employee or former employee of the Office of Administration shall, in response to a demand of a court or other authority, produce any material contained in the files of the Office of Administration or *disclose any information* or produce any material *acquired as part of the performance of his official status* without the prior approval of the Deputy Director." (emphasis added). The rule requires that "[i]f possible, the Deputy Director shall be notified before the employee or former employee concerned replies to or appears before the court or other authority." 5 C.F.R. § 2502.32(a). Here, the nature of Mr. Jennings's requested testimony, the unavailability of the sought information from other means, and the testimony's alignment with the government's interests merit your authorization.

1. Nature of the Requested Testimony

Mr. Jennings would testify regarding his knowledge of the Government's use of average wholesale price ("AWP") as a basis for reimbursement for drugs under Medicare Part B. This testimony would be based on Mr. Jennings's tenure as the President's Senior Health Policy Advisor from 1993 to 2001. Mr. Jennings was also a Congressional Health Care Advisor from 1983 to 1993, serving as a committee staff member for three U.S. Senators.

Specifically, Mr. Jennings would testify to his knowledge or understanding of the Government's use of AWP for reimbursement, the relationship between AWP and provider acquisition costs, the extent to which reimbursement for drug ingredients operated as a cross-subsidy for the inadequate reimbursement of the costs of service and administration, the reasons for maintaining AWP as part of Medicare reimbursement, and the general operation of the reimbursement system. These issues are relevant to the AWP litigation.

2. Availability from Other Means

The information that could be gleaned from the testimony of Mr. Jennings is unavailable through other means. Specifically, Mr. Jennings provides a unique perspective as the Clinton Administration's Senior Health Advisor during pivotal years when the Administration attempted to reform the Medicare system for the reimbursement of prescription drugs. After recounting the Administration's proposed changes in 1997 and 2000, the *New York Times* quoted Mr. Jennings as calling the current system "unsustainable." Robert Pear, *Administration Plans Cuts in Some Drug Payments*, N.Y. TIMES, Aug. 6, 2000 at 12, attached hereto as Ex. 3.

"consolidated plaintiff" on the docket, it has moved to appear as an "interested party," it has intervened in a matter transferred to the MDL, and it has filed an *amicus* brief in the instant case. The instant letter in no way waives our position, which is equally applicable to potential testimony from Mr. Jennings.

Based on this experience, Mr. Jennings is able to offer a unique perspective on the Government's use of AWP as a basis for reimbursement under Medicare Part B. The *St. Peterburg Times* identified him as the health policy advisor dealing with the issue of AWP during the Clinton Administration. He stated: "Report after report concludes the same thing every time. It says we're way overpaying for these drugs. But members of Congress can't agree among themselves how to fix it, and it doesn't hurt that the oncologists are lobbying everyone." Sara Fritz, *Medicare Markup for Drugs: 10,000%*, ST. PETERSBURG TIMES, July 14, 2002 at 1A, attached hereto as Ex. 4. It is this kind of perspective that Mr. Jennings can offer the Court.

3. Interests of the Office of the Administration

Allowing Mr. Jennings to testify is in the best interest of the Government. In almost five years of litigation, the parties have disputed the Government's understanding of the AWP system used in the industry, as well as the Government's decision to use AWP as a basis for reimbursement under Medicare Part B. The United States has taken an active role in this dispute: appearing as a "consolidated plaintiff" on the docket, moving to become an "interested party" in this litigation, and intervening in a similar AWP matter, *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs., et al.*, now pending before the MDL Court. In this context, Judge Saris, who is presiding over this case, has recognized the potential benefit of a government witness to explain the use of AWP as a basis for reimbursement under Medicare Part B. (Tr. of Aug. 3, 2006 Hr'g at 19-20, attached hereto as Ex. 5.). The testimony of Mr. Jennings, as described *infra*, would be such testimony.

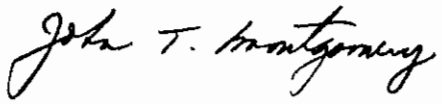
Moreover, the primary justification for denying so-called *Touhy* requests – the conservation of agency resources – is absent in this case. *See, e.g., Moore v. Armour Pharmaceutical Co.*, 927 F.2d 1194, 1197-98 (11th Cir. 1991) (recognizing that requiring *current* DHHS doctors to testify would interfere with the agency's "interest in maximizing the use of its limited resources in dealing with a national health crisis"); *Reynolds Metals Co. v. Crowther*, 572 F. Supp. 288, 290 (D. Mass. 1982) (recognizing that if *current* "OSHA employees were routinely permitted to testify in private civil suits, significant loss of manpower hours would predictably result"). In the instant case, since Mr. Jennings is a *former* employee, the primary reason for denying *Touhy* requests – the conservation of governmental resources – does not exist.[3]

For the foregoing reasons, 5 C.F.R. § 2502.31 warrants your authorization of Mr. Jennings to testify in the above-referenced litigation. As stated, this matter is scheduled for trial

[3] In fact, should the agency deny this request, it "may even be more costly to the agency in the long run than allowing the employee to testify when originally requested" due to costs defending the agency decision. Robert R. Kiesel, *Every Man's Evidence and Ivory Tower Agencies: How May a Civil Litigant Obtain Testimony from an Employee of a Nonparty Federal Agency?*, 59 Geo. Wash. L. Rev. 1647, 1670-71 (1991).

beginning on November 6, 2006, and Judge Saris has expressed interest in hearing testimony from government witnesses. Under the circumstances, we respectfully ask that you notify us as soon as practicable, and no later than one week from today, October 24, 2006. If you have any concerns, we would be pleased to speak with you at your earliest convenience.

Very truly yours,



John T. Montgomery

JTM/tw
Enclosures

cc: Gejaa T. Gobena
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EXHIBIT 1

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Re: *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL 1456

Dear Mr. Gobena and Mr. Henderson:

I write on behalf of the Track 1 Defendants in the above-referenced litigation ("Defendants") concerning current or former government employees, particularly of the Center for Medicare and Medicaid Services ("CMS"), who may testify at the upcoming November trial.

You will recall that Judge Saris asked the parties at the hearing on August 3 whether any current or former government employees would be called as witnesses at the trial in November, and if so, she noted that the parties should consider the implications of the so-called *Touhy* regulations. *See* 45 C.F.R. § 2 *et. seq.* These regulations set forth a procedure for notice of the intention to call a former government employee of an agency of the Department of Health and Human Services as a witness and for a response from the head of the relevant agency, in this instance the Administrator of CMS.

We have reviewed the regulations, however, and they are not applicable to this proceeding. The United States appears as a "consolidated plaintiff" on the docket, and it has moved to appear as an "interested party" in MDL No. 1456, a motion which was granted by the Court. Additionally, the United States has intervened in a matter, *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs., et al.*, which was recently transferred to MDL No. 1456 and is now pending before this Court. Accordingly, we do not believe the regulations are applicable. *See id.* at 2.1(d)(1).

The Defendants do intend to present one or more current or former employees of CMS as witnesses at trial. Even if the *Touhy* regulations were applicable here, which they are not, it is clear that any testimony from a current or former CMS employee would merit approval from the CMS Administrator. As you know, Judge Saris has expressed her desire to hear from such

witnesses regarding the use of AWP as a basis for reimbursement of prescription drugs under Medicare Part B. Certainly, it would "promote the objectives of the Department," as provided in 45 C.F.R. § 2.3, to permit current or former employees of CMS to comply with the Court's request for testimony concerning these issues. The Defendants also believe that the testimony would be relevant to the development of a complete and accurate record on the issues presented for decision

If you would like to discuss the foregoing, we would be please to speak with you at your earliest convenience.

Very truly yours,

John T. Montgomery

EXHIBIT 2

U.S. Department of Justice

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September 12, 2006

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Re: In re Pharmaceutical Industry Average Wholesale Price Litigation, MDL No. 1456 (D. Mass.)

Dear Mr. Montgomery:

On behalf of the Department of Health and Human Services (HHS), I am responding to your letter of August 31, 2006, in which you set forth the Track 1 Defendants' position that the HHS Touhy regulations do not apply to the MDL proceedings.

Your position is meritless. The fact that the United States is a plaintiff in a case that has been transferred to MDL No. 1456 does not make the United States a "party" to any of the class action cases, including the Track 1 case scheduled for trial in November. The transfer of the government's case to MDL 1456 was for pretrial purposes only. The United States moved to appear in the MDL as an "interested party" solely to facilitate electronic filing of documents, as the motion indicates. Judge Saris has already indicated her view that the United States is not a party to the Track 1 class action cases and that the Touhy regulations apply. *See* August 3, 2006, Status Conference Hearing Transcript at 18:15 - 20:2.

If the Track 1 Defendants seek the testimony of a present or former government employee concerning information acquired in the course of performing official duties or because of the person's official relationship with the Department, then the Defendants must comply with the Department's regulations at 45 C.F.R. § 2 et seq. Any request for testimony "must be addressed to the Agency head in writing and must state the nature of the

requested testimony, why the information sought is unavailable by any other means, and the reasons why the testimony would be in the interest of [HHS] or the federal government." 45 C.F.R. § 2.4.

Sincerely,

George B. Henderson, II
Assistant U.S. Attorney

cc: Gejaa T. Gobena
Carol Bennett

EXHIBIT 3

The New York Times

August 6, 2000, Sunday, Late Edition - Final

SECTION: Section 1; Page 12; Column 5; National Desk

LENGTH: 1275 words

HEADLINE: Administration Plans Cuts In Some Drug Payments

BYLINE: By ROBERT PEAR

DATELINE: WASHINGTON, Aug. 5

BODY:

In an effort to save money for Medicare, the Clinton administration is planning to cut payments for anticancer drugs administered to patients in doctors' offices. This could affect hundreds of thousands of elderly patients.

The move has provoked an outcry from patients, doctors, nurses and members of Congress, who say the cuts will make it financially impossible for many cancer specialists to provide chemotherapy in their offices.

Donna E. Shalala, the secretary of health and human services, says the cuts are justified because Medicare, the federal health insurance program for the elderly and disabled, is paying too much for the drugs -- far more than doctors pay for many of the medicines.

Dr. Shalala said the government would reduce the "excessive Medicare payments" later this year, perhaps as early as Oct. 1, because federal investigators had obtained more accurate data showing what doctors actually paid for the drugs.

Doctors said they would send many of their Medicare patients to hospitals for treatment, causing inconvenience to patients while increasing costs to Medicare.

Representative Nita M. Lowey, Democrat of New York, said: "I am very concerned about the impact of these cuts on cancer patients. Many oncologists will find that it's financially impossible to provide chemotherapy services in their offices."

Doctors confirm that they receive more than they pay for some drugs, but insist that the extra payments are essential to cover chemotherapy costs not reimbursed by Medicare.

The dispute illustrates the passions aroused when the fate of cancer patients gets mixed up in debates over drug prices and doctors' income.

At least 120 members of Congress -- 69 Republicans and 51 Democrats -- have signed letters to Dr. Shalala expressing alarm about the administration's plans. Many complained that the administration appeared to be acting unilaterally, without soliciting public comment, as agencies usually do before making major changes in federal regulations.

Dr. Joseph S. Bailes, former president of the American Society of Clinical Oncology, which represents 15,000 cancer specialists, urged the White House to "reconsider and rescind these cuts." He estimated that 750,000 Medicare beneficiaries received chemotherapy in doctors' offices each year. Most have cancer of the breast, colon or lung.

Chris Jennings, the health policy coordinator at the White House, said he was not surprised at the criticism from cancer specialists because they derived substantial amounts of income from Medicare's payments for drugs. He said the White

House had asked Medicare officials to assess whether the cuts would harm access to care or the quality of care.

"Patients should not be hurt in any way, but taxpayers should get a fair deal," Mr. Jennings said in an interview this week. "The current reimbursement policy is unsustainable. It's appropriate to reimburse doctors for the cost of the drugs they purchase, but they should not be allowed to mark up the price by 20, 70 or 700 percent, as they do now in some cases."

A 1997 study by the Department of Health and Human Services said that Medicare payments for 22 drugs, including many cancer drugs, exceeded the actual wholesale prices by 29 percent, or $447 million, in 1996. For 8 of the 22 drugs, it said, Medicare paid more than twice the actual wholesale price.

In the last decade, most cancer chemotherapy has shifted from hospitals to doctors' offices. Doctors say the cuts in Medicare payments would reverse that trend.

Medicare's policy is important for two reasons. At least half of all patients receiving chemotherapy in this country are on Medicare, cancer experts said. Private insurers, which cover other patients, often follow the government's example and could be expected to lower their reimbursement rates as well.

"This is not just a threat to the Medicare program," Dr. Bailes said. "It's a threat to cancer care in general."

Ellen L. Stovall, executive director of the National Coalition for Cancer Survivorship, a patients' group, said, "I'm not interested in helping the physician make more money, but I am worried that patients may have less access to care as an inevitable and unintended consequence of these cuts."

Dr. Barton C. McCann, who was the chief medical officer of the Medicare program from 1986 to 1998, said the cuts "may have the unintended consequence of making it financially impossible for oncologists to treat patients in their offices." If Medicare beneficiaries cannot receive chemotherapy there, Dr. McCann said, they will seek it at hospitals, where care is more expensive, and "total costs to the Medicare program could rise" as a result.

Medicare generally does not pay for prescription drugs outside a hospital, but there are exceptions. Medicare does, for example, pay for drugs provided "incident to a physician's service," including cancer drugs given to patients by injection or infusion in a doctor's office.

Doctors receive separate payments for the drugs and for the service provided when they or their nurses administer the drugs.

The doctors acknowledge that they can buy some cancer drugs, especially older drugs, at prices lower than what Medicare pays. But, they say, Medicare pays much less than what it costs to administer the drugs. Federal officials agree that the doctors' "practice expenses," including the costs of medical staff, supplies and equipment, far exceed the amounts recognized by Medicare.

For years, doctors say, the markup on cancer drugs has partly offset the inadequacy of the payments for administering chemotherapy.

Before 1998, Medicare paid doctors the average wholesale price of cancer drugs. Payments were reduced by a 1997 law, which said that Medicare would pay "95 percent of the average wholesale price," but the law did not specify how that price should be determined.

In 1999 and again this year, President Clinton proposed a further cut. He wanted to pay 83 percent of the average wholesale price. Mr. Clinton said that would "eliminate the physician markup for outpatient drugs." Dr. Shalala said the cut would save Medicare $2.9 billion over 10 years.

Congress has rejected that approach, but Clinton administration officials said they had found a way to achieve a similar result by different means. They intend to redefine "average wholesale price" to reflect the lower prices that they now believe are available to doctors.

For years, the government obtained wholesale prices from trade publications like the Red Book, published by Medical Economics, a unit of the Thomson Corporation.

Representatives Saxby Chambliss, Republican of Georgia, and Ken Bentsen, Democrat of Texas, said "wholesale price" was understood by Congress to mean the price listed in such publications.

But now, Dr. Shalala said, the government will use the data it recently obtained from catalogs of certain drug wholesalers. The Justice Department compiled the data in an investigation of drug pricing under Medicaid, a separate program.

By redefining "average wholesale price" in this way, federal officials said, they can reduce payments for drugs without any change in federal law or regulations.

"This is the most immediate action we can take without undergoing the formal rule-making process," Dr. Shalala said.

Mr. Chambliss said the question of how to pay for cancer drugs had been repeatedly addressed by Congress in the last few years. "It is," he said, "disturbing that the Department of Health and Human Services would seek to circumvent those Congressional actions by unilaterally adopting a new definition of average wholesale price."

http://www.nytimes.com

LOAD-DATE: August 6, 2000

EXHIBIT 4

July 14, 2002 Sunday 0 South Pinellas Edition

SECTION: NATIONAL; Pg. 1A

LENGTH: 2154 words

Medicare markup for drugs: 10,000%

BYLINE: SARA FRITZ

DATELINE: WASHINGTON

BODY:

For years, federal investigators have been churning out reports showing that physicians are overcharging Medicare for the chemotherapy drugs used to treat cancer patients.

Doctors who pay only $7.75 for a single dose of Vincasar, for example, are reimbursed at a rate of $700 under Medicare. The government covers $560, and the Medicare patient pays $140.

Both the Clinton and Bush administrations have tried unsuccessfully to trim the Medicare overpayments, which are estimated to cost American taxpayers $2-billion a year.

"There must be no room for waste, fraud and abuse in Medicare," President Clinton declared emphatically in one of his many such appeals to Congress.

Congress, under intense pressure from oncologists and drug manufacturers, usually rejects such entreaties.

In 1997, legislators thumbed their noses at Clinton by formally tying the reimbursements to a controversial drug industry benchmark known as "average wholesale price." Despite its name, AWP is not the average price paid by wholesale purchasers. Instead, it serves as a kind of "sticker price" used by the drug companies to open price negotiations, and it far exceeds what doctors actually pay for the drugs.

Bruce Vladeck, who headed the agency that oversees Medicare under Clinton, says this long history of overpayments points up the biggest unspoken risk involved in Congress' current efforts to create a full prescription drug benefit for seniors under Medicare: As unlikely as it seems, no one in government has been able to determine the actual market price of drugs.

"It's clear that for many drugs, there is no real market price," said Vladeck, now the interim chairman of the geriatrics department at Mount Sinai School of Medicine. "These prices can be manipulated. You have to be careful about the pricing rules, or the government is going to get ripped off."

Almost everyone profits

As cancer survivors will attest, chemotherapy is both unpleasant and expensive.

Toxic drugs are administered to the patient through a syringe for anywhere from 20 minutes to several hours. The procedure is handled by a specially trained nurse, who monitors the patient for side effects such as nausea or vomiting.

According to the American Society of Clinical Oncology, the standard treatment for a Medicare patient with metastatic breast cancer - six courses of a combination therapy of Taxol and Herceptin - can cost about $24,000. Treatment

for a patient with advanced nonsmall cell lung cancer with Gemzar and Platinol is around $15,000.

Medicare has long had the power to set reimbursement rates for doctors and hospitals, but the pharmaceutical industry has convinced Congress that price controls on its products would stifle drug innovation. That is why drugs are handled in a different way.

When Medicare patients regularly received chemotherapy as hospital inpatients, the reimbursement cost of these drugs was not an issue. Hospitals got a set reimbursement for inpatient treatments that was meant to cover all costs including beds, staff, drugs, food and medical supplies. That eliminated the problem of having to estimate how much to pay for any single item, such as drugs.

In the 1980s, when patients began receiving chemotherapy as outpatients instead of checking into a hospital for it, Medicare officials faced a dilemma. The government did not pay for outpatient drug treatments, but chemotherapy was too expensive for most seniors to finance themselves. Cancer patients succeeded in persuading the government to foot the bill.

Thus began a continuing political struggle to determine how to reimburse doctors for outpatient drug treatments.

Oncology doctors already were receiving reimbursement for their services, but it was hard to figure out how much to add for drugs because the pharmaceutical companies were giving oncologists a wide variety of undisclosed discounts.

Initially, Medicare officials decided that oncologists would be paid according to AWP, a price listed in the Red Book, an industry guide published by the Medical Economics Co. By the time federal authorities realized how drastically AWP overstated the true wholesale price, it had already become the benchmark for reimbursement.

The drug manufacturers soon discovered they could sell more of their drugs by simply inflating the AWP figure. The higher these companies set AWP, the bigger the profit they could offer to doctors and hospitals who used their products to treat Medicare patients.

Under Vladeck, government officials began to recognize the problem in the early 1990s when they saw a dramatic increase in the number of Medicare claims for Luperon, which is used to treat prostate cancer. They eventually found that TAP Pharmaceutical Products Inc. was routinely providing free samples to physicians, who then charged Medicare for the drugs using a highly inflated AWP.

The TAP case was uncovered about the same time Bayer Corp. was found guilty of setting unusually high AWPs for several drugs used to treat hemophilia and immune deficiency diseases to defraud Medicaid. TAP wound up paying $875-million in the largest health care fraud settlement in history; Bayer settled for $14-million.

The two settlements have spawned a variety of pending legal actions against drug manufacturers by states, unions and consumer groups.

Embedded in the system

"It is simply unacceptable for Medicare to continue paying for drugs in an outdated, noncompetitive way that costs beneficiaries and the program far more than it should," says Tom Scully, current director of the Centers for Medicare and Medicaid Services.

"Simply unacceptable" is the same phrase Clinton used in a radio address in December 1997 to describe the problem. "Sometimes the waste and abuses aren't even illegal," Clinton continued. "They're embedded in the practices of the system."

For at least a decade, Americans have heard government officials pledge to trim Medicare reimbursements for outpatient drugs. Under some of the failed proposals put forth by the Clinton and Bush administrations, doctors would have been reimbursed at a rate of 85 percent of AWP, at 83 percent of AWP, at the

prices listed in the company sales catalogs, at the actual cost of acquiring the drug and at an estimated wholesale price below AWP.

Congress tried to put an end to the debate in 1997 by setting payments at 95 percent of AWP. While AWP had always been used as a benchmark, this was the first time it was written into law.

Both the General Accounting Office and the Department of Health and Human Services inspector general have since done many studies showing that 95 percent of AWP is too high. But they have never been able to propose an average price that would fairly compensate all oncologists.

The huge markup on Vincasar came to light in June when Minnesota Attorney General Mike Hatch filed suit against Pharmacia, the drug's manufacturer. The suit says that most doctors pay only $7.75 for the drug, even though the published AWP is $742.50.

Even inexpensive drugs cost Medicare more than they should.

Janet Rehnquist, Health and Human Services inspector general, estimates Medicare could have saved more than $178-million in 1999 if physicians had been paid the catalog price of 13 cents per milligram for albuterol sulfate (used to treat lung diseases) instead of 47 cents, which is 95 percent of AWP.

When Rehnquist studied 24 drugs commonly administered to Medicare outpatients, she found the government could have saved a total of $887-million in 2000 simply by reimbursing physicians at the wholesale catalog price instead of AWP. Her study did not include the newest, most expensive drugs such as Vincasar.

"Report after report concludes the same thing every time," noted Chris Jennings, a domestic adviser to Clinton who handled this issue at the White House. "It says we're way overpaying for these drugs. But members of Congress can't agree among themselves how to fix it, and it doesn't hurt that the oncologists are lobbying everyone."

Political pressures

Oncologists have been unusually successful in beating back efforts to revise Medicare's reimbursement formula for outpatient drugs.

The American Society of Clinical Oncology is a fast-growing, 16,600-member organization with influential doctors in every congressional district. It also gets generous funding from the pharmaceutical manufacturers. Its Web site lists 25 drug companies that have contributed at least $20,000 to the group in the form of unrestricted educational grants.

Numerous well-organized cancer survivor groups also assist the group in lobbying Congress.

Among the many members of Congress it counts among its friends is Rep. Nancy Johnson, R-Conn., chairwoman of the House Ways and Means health subcommittee, who has been instrumental in preserving the AWP-based reimbursement.

For her consistent support, Johnson received the National Cancer Medal of Honor in April from U.S. Oncology, a national network of community-based cancer centers. The group said, "Johnson shares a deep commitment to helping cancer patients and their families maintain access to the community-based cancer care they need."

Lobbyists for oncologists and cancer patients argue that any effort to trim the payments will force doctors to check their chemotherapy patients into hospitals, which are not equipped to handle such a load, or establish waiting lists for people seeking cancer treatments.

"It is acknowledged that Medicare overpays for cancer drugs, but also widely recognized that Medicare pays less than actual cost of administering those drugs," the Cancer Leadership Council, which includes the American Society of Clinical Oncology, said in a December letter to members of Congress. "If Con-

gress is to address the problem of drug overpayments, it must simultaneously resolve the corresponding underpayment for practice expense."

Philip Johnson, pharmacology director for H. Lee Moffitt Cancer Center & Research Institute in Tampa, says proposals to trim the reimbursements are like "trying to buy a prime rib for the price of a cheeseburger.

"The government is setting up a scenario where the hospitals are going to look bad and the people won't get the treatment they need," he said.

Presidential politics has played a big role in preserving the current system.

In 2000, the Clinton administration backed away from a proposal to rein in the payments. Administration officials decided to retract the proposal after then-Texas Gov. George Bush, the Republican nominee, suggested the Democratic initiative would undermine health care for Medicare patients.

"The White House folks didn't want to go up against the oncologists," said Vladeck.

Using government power

Only recently has the word "competition" entered into the debate over Medicare reimbursements for outpatient drugs.

Members of Congress now see competition as a possible way to limit drug prices without imposing actual price controls. The House-passed bill that would create a prescription drug benefit for all seniors calls for a mild form of competition between companies chosen to manage the pharmacy benefits.

For outpatient drugs, some members of Congress say Medicare should follow the example of the Veterans Administration, which awards contracts to the wholesaler that offers to sell a drug to the VA for the lowest price. Because Medicare covers more patients, they reason, it should get an even bigger discount than the VA.

According to Rehnquist's study of 24 drugs given to outpatients under Medicare, the government could have saved $1.6-billion in 2000 if it had paid for them according to the VA's price list. For half of these drugs, she said, Medicare pays more than double the VA price.

Medicare pays about $173.49 for 30 milligrams of Taxol, which is used to treat ovarian and breast cancer, while the VA pays only $107.59 - a savings of 38 percent. Medicare pays 47 cents for a milligram of albuterol, and the VA pays 85 percent less at 7 cents.

But there is not enough support in Congress for this idea to be adopted.

The Ways and Means Committee is considering a compromise plan under which the government would solicit bids from pharmaceutical suppliers and then offer to pay the average of those prices. In other words, Medicare, unlike the VA, would not buy from the lowest bidder. The legislation apparently would offer no incentive to preclude the companies making wildly exaggerated bids to drive up the average.

Vladeck says the government will never be able to get control of Medicare costs until Congress gets over the idea that it is wrong to use the government's buying power to get discounts.

"It's idiotic not to use the market power of the federal government to get lower prices," he says. "We're just unwilling to admit that we're really controlling drug prices."

LOAD-DATE: July 14, 2002

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re:	)	
PHARMACEUTICAL INDUSTRY	)	CA No. 01-12257-PBS
AVERAGE WHOLESALE PRICE	)	MDL No. 1456
LITIGATION	)	

STATUS CONFERENCE
BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 3, 2006, 4:25 p.m.

LEE A. MARZILLI
CERTIFIED REALTIME REPORTER
United States District Court
1 Courthouse Way, Room 3205
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P R O C E E D I N G S

THE CLERK: In re: Pharmaceutical Industry Average Wholesale Price Litigation, Civil Action No. 01-12257, MDL 1456, will now be heard before this Court. Will counsel please identify themselves for the record August 3, 2006.

MR. SOBOL: Good afternoon, your Honor. Tom Sobol for the plaintiffs.

THE COURT: Good afternoon.

MR. SPECTER: Good afternoon. Shanin Specter, plaintiffs.

MR. HAVILAND: Don Haviland, your Honor, for the plaintiffs.

MR. BERMAN: Steve Berman, your Honor.

MR. EDWARDS: Steve Edwards, BMS.

MR. MONTGOMERY: John Montgomery, Schering-Plough and Warrick.

MR. WISE: Scott Wise for AstraZeneca, your Honor.

MR. CAVANAUGH: Bill Cavanaugh, Johnson & Johnson.

MR. DeMARCO: Michael DeMarco, Aventis.

MR. MUEHLBERGER: Jim Muehlberger, Aventis.

MR. STEMPEL: Scott Stempel, Pfizer and Pharmacia.

MR. GOBENA: Your Honor, I would just like to let you know the United States --

THE COURT: Has arrived. Actually, why don't you come on up here.

MR. GOBENA: All right.

THE COURT: And I'm going to ask the USA something ex parte for one second because there's something that was just transferred up here, and I'm not sure --

MR. GOBENA: Your Honor, should we identify ourselves for the record?

THE COURT: Yes, do that, because I didn't know there were so many of you all.

MR. GOBENA: My name is Gejaa Govena. I'm with the Justice Department.

MR. HENDERSON: George Henderson, Assistant U.S. Attorney.

MR. BREEN: Jim Breen for the relator Ven-A-Care, the 402s.

THE COURT: All right, then we know. All right, I just didn't know if that's public.

MR. HENDERSON: It is as a matter of the caption of the case.

THE COURT: All right, so why don't at least one of you sit here. The case involving -- you've stepped in and decided to intervene, is that it?

MR. GOBENA: That's correct, your Honor.

THE COURT: The government has? Are you all familiar with what I'm talking about?

MR. MONTGOMERY: Yes, your Honor.

MR. CAVANAUGH: Yes.

THE COURT: All right, so you get a table to yourself.

MR. DALY: Your Honor, just for the record, Jim Daly. I'm here for Abbott Labs, the company that the government intervened with respect to.

THE COURT: Okay, thank you very much. I wasn't sure, because I just got notice of it through the MBD docket, whether it was still sealed or not, and that was why I wanted to make sure that I checked that out before I spilled it out in front of this entire room. But it's now public. The Department of Justice is here, right?

MR. GOBENA: That's correct, your Honor.

THE COURT: All right, so what is your position in general in this case? I haven't had a chance to even go through what the case is about from the Justice Department's point of view.

MR. GOBENA: Sure, your Honor. As your Honor has noted, we've intervened in a case that originated in the Southern District of Florida against -- the defendants in the case are Abbott Labs and Hospira as well --

THE COURT: And?

MR. GOBENA: Hospira, which was a spin-off of Abbott Labs, and what was spun off was the division that manufactured the drugs that were identified in our complaint.

THE COURT: Yes, but what's the case? Was it an AWP case?

MR. GOBENA: It's a False Claims Act case alleging AWP pricing fraud, so it's the same general subject matter as these cases, but we're bringing it under the False Claims Act as well as we have an unjust enrichment claim and a common law fraud claim as well.

THE COURT: And just so I can get a lay of the land -- you may not be prepared to answer this question -- is this just going to be limited to these drugs involving Abbott, or are you going to have a stake in the rest of this litigation?

MR. GOBENA: We're really not prepared to answer that question at this time, your Honor, but it's fair to say that there may be additional defendants that enter into our case.

THE COURT: All right, thank you. Right now, I thought it would be worthwhile to ask the plaintiffs how much they've accomplished in their notice, since that essentially is the threshold to doing anything, what's been sent out, what hasn't been -- oh, there you are.

MR. NOTARGIACOMO: Good afternoon, your Honor. Ed Notargiacomo for the plaintiffs. We are on track with everything your Honor has ordered us to do. On Friday , July 28, we mailed all of the TPP notices.

THE COURT: Third-party payor, right.

MR. NOTARGIACOMO: Third-party payor notices. The Web site for third-party payors, that version of the Web site went live on Monday, so that as those third-party payors receive the notices, additional information is available. The same thing with the phone bank available to answer third-party payor questions about it as they receive the notices. We are on track with the consumer --

THE COURT: So just remind me. Is that just Track 1 third-party payors, or is it Track 2 as well?

MR. NOTARGIACOMO: It is just Track 1 third-party payors, your Honor.

THE COURT: And just in Massachusetts?

MR. NOTARGIACOMO: Well, the third-party payors could be anywhere in the United States.

THE COURT: Right, but just with respect to the Massachusetts 93A claim.

MR. NOTARGIACOMO: That's right.

THE COURT: Yes, I misspoke. All right, so that's going forward just on people who have claims under the Massachusetts statute with respect to third-party payors just for Track 1?

MR. NOTARGIACOMO: Yes, your Honor. The notice included notice to third-party payors who would be in Class 2 as well as Class 3.

THE COURT: All right, so for everyone. I don't have to worry about them again.

MR. NOTARGIACOMO: That's correct.

THE COURT: What about, when's the opt-out date? What did we end up with?

MR. NOTARGIACOMO: I believe October 1, 2006.

THE COURT: Now, as I understand it, and I don't know if you all saw this, I got a report from the Department of Health and Human Services yesterday through Mr. Henderson which basically said that, much more polite language, but basically no way are they going to let the notice go in the Medicare bulletin, legalese for "over my dead body." So at this point I think that that is a moot issue. It's too expensive; they don't want it. It's not worth the holdup to litigate the thing. Does anyone feel differently about that?

Okay, so we're back with the individualized notice. And, Mr. Henderson, are we on track for that? Have you checked?

MR. HENDERSON: I haven't checked recently. I've certainly let the agency know of your order, and I haven't heard anything, anything suggesting that they can't meet it. I can certainly follow up to make sure.

THE COURT: Okay, so what I want you to do is every month check.

MR. HENDERSON: All right.

THE COURT: Because, as you can tell, I'm really moving this at this point, and I'm counting on a Class 1 trial in March.

MR. HENDERSON: All right, I'll put that on my calendar.

THE COURT: You know, just tickler it in every month, write me a little status report just to make sure we're on track because I've got this whole thing triggered to a March date.

MR. NOTARGIACOMO: All right.

THE COURT: All right, that's great, with respect to Class 1.

Now we're dealing with September and November, the two time periods. I've had a chance to briefly read your submissions because I didn't get them till late yesterday, and I was on trial all day today and haven't had a chance to return to them. So the gist of it is, as I understand it, everyone agrees nothing will happen as far as the trial in September. There's a disagreement about November, about whether there should be any proceeding and what it should look like. You want to do Daubert in September.

MR. MONTGOMERY: Correct, correct.

THE COURT: But I'm just talking about the trial, a basic merits proceeding, which we are going to get to. I'm

going to do something in November. I've locked it up, I have staffed up, and that's what we're going to do. So I reject plaintiffs' request to move everything into March. I reject defendants' request to just do knowledge. Knowledge is a piece of it. The plaintiffs have ignored the fact that knowledge is relevant because I have a statute of limitations problem. I've got a discovery rule. At the very least, we have to find out what they knew and when they knew it for when the discovery rule tolled, although you might be quite right that it isn't dispositive on a 93A claim.

In addition, knowledge is quite relevant to reasonable reliance, especially in the world of Class 3. So I will take whatever I learn in the trial in November, and I will use it in dealing with the Class 3.

Class 2 is more of a statutory kind of claim, although I still have the intent to deceive, and that intent-to-deceive knowledge has some relevance as to whether or not there was an intent to deceive. So knowledge is relevant, but it's not dispositive.

MR. MONTGOMERY: Your Honor, we apologize that your Honor did not receive our paper earlier. I think our concept about how to proceed in November is to focus, in order to avoid any overlap with Class 1, on the conduct of the TPPs and the context in which they were operating during the class period, for your Honor to take all of the evidence that the

parties would present with respect to that scope. And at some point, of course, you're going to have to determine the issues to which that evidence is relevant. We certainly have a disagreement about the relevance of this evidence, but certainly it is relevant to the statute of limitations issue, and that's why we focused on statute of limitations.

THE COURT: Right.

MR. MONTGOMERY: But we think it's broader.

THE COURT: I think that I want to jump start this for lots of reasons. One is, this litigation is too slow. I'm starting myself to feel bogged under by it without an end in sight. I think, to the extent that I hold a trial, I will get a handle on the issues in a way that will make me a better trial judge for the actual jury trial. Two, I think it will facilitate people taking a good look at whether settlement is in their best interests; and, three, I can sort of figure out as I'm going some of the expert issues without having to have a major new Daubert hearing. I was thinking of possibly -- are you going to be calling your witness in any event for that --

MR. BERMAN: Our expert witness?

THE COURT: Yes.

MR. BERMAN: Yes, we are, your Honor.

THE COURT: So one thought I have is, since you're paying him by the day anyway, I'm sort of assuming, I would

see him some of the afternoons on the Track 3 expectation kind of theory.

MR. BERMAN: Correct.

THE COURT: Does that make sense?

MR. BERMAN: We were going to suggest that you can do any Daubert-ing while you're listening and they're cross-examining at that hearing.

THE COURT: So I'm going to do Track 1, Class 2, in November.

Now, I don't know what plaintiff is thinking about when you're talking about -- what was it, 20 hours a side for a 93A? That was what you were talking about?

MR. BERMAN: Well, what we think we need to do --

THE COURT: You think you're going to do a two-month trial?

MR. BERMAN: No, we don't. We think we need roughly five to seven days --

THE COURT: Three and a half hours a day.

MR. BERMAN: -- to get in everything we need to get in on knowledge.

THE COURT: No, no, no, this is the whole -- catch this -- the whole. It's not just knowledge. You're going to prove your case, if you can.

MR. BERMAN: Correct.

THE COURT: So I don't know why it's just

knowledge. You think you can do seven trial days to try your -- so we'll do -- we'll have a three-week trial.

MR. BERMAN: Correct. We can get our liability case out in five to seven trial days.

THE COURT: But what about damages?

MR. BERMAN: And damages.

THE COURT: Okay, so seven trial days.

And what do you think you need?

MR. MONTGOMERY: Your Honor, if you're talking about trying the entire case on Class 2 and Class 3 --

THE COURT: No, just Class 2.

MR. MONTGOMERY: Just Class 2, and then you're talking about doing Daubert --

THE COURT: And there may be some overlap that I'll just, you know, import into a Class 3. I'm assuming a fair amount will --

MR. MONTGOMERY: Yes, but to just talk about Class 2 and Class 3 together for a second, and just starting with statute of limitations but extending to other issues, we've got the same class representatives, the same kinds of issues, the same conduct focusing on the TPP part of the story. So it's the same for Class 2 and Class 3 until you get to the edges. It's exactly the same.

THE COURT: Well, the edges, though, are the really hard economic issues because one's a statutory claim and

one's sort of more of a, was there an unfair or deceptive practice that somehow inflated the price in a way the TPPs couldn't have known? So you may think it's identical or not. I haven't thought it through --

MR. MONTGOMERY: We do, and I know we need to have more discussion, and this is not the time to do it.

THE COURT: You need to have more discussion about it, but, in any event, damages will vary dramatically.

MR. MONTGOMERY: Damages will vary.

THE COURT: Okay, so it's possible liability is the same. I really haven't given it any thought, so. . . I'd be willing to consider Track 2 and 3, but I want the whole thing. I want people to really focus on this. How many defendants are going to be in Track 1, four or five?

MR. BERMAN: Just four, your Honor.

MR. MONTGOMERY: No. In Track 1 there are three. Oh, excuse me, Class 1 is three. Track 1 is four. Excuse me.

MR. BERMAN: Four, and the fifth will -- we're almost there. Next week.

THE COURT: The check's in the mail?

MR. SOBOL: Yes.

MR. BERMAN: Next week.

MR. SOBOL: The check's in the mail.

THE COURT: So that's where we'll go on it in

November. But let's assume for a minute you're right, that it ends up being both classes and I can maybe do the Daubert hearing sort of simultaneously with the bench trial so that we're not wasting additional time, how much time will it take?

MR. MONTGOMERY: Yes, I mean, this here is a lot more complicated, your Honor, because if we're not talking any longer as we were a month ago about the TPPs' conduct, that evidence, and we're talking about the individual conduct of each of four companies --

THE COURT: Right.

MR. MONTGOMERY: -- that we haven't thought about. I think we need to confer. We've got four separate cases.

THE COURT: I do, I agree. That's why I'm asking this.

MR. MONTGOMERY: And so I think I need to confer and we need to talk about that. We can do that right now, but that's a --

THE COURT: So you can prove against four separate defendants in seven days?

MR. BERMAN: Yes, your Honor. We planned it out. We've been anticipating this.

THE COURT: Okay.

MR. MONTGOMERY: May we have a moment?

THE COURT: Yes. You know, you don't have to do

this on the fly. I mean, it's --

MR. MONTGOMERY: We think it's a long time. I mean --

THE COURT: Well, I'm not going to probably give you everything you want because in a bench trial, I can play with different ideas, like you can submit the direct by affidavit, and then we can do cross, or you can do the direct by affidavit and then do maybe an hour or two just to sort of bring me along, if you will, to highlight your big points and then have cross. There's so much we can do, and I know this case at this point, so I don't need background on the industry so much. It's always good to refresh my recollection because there's the WACs and the MACs and, you know, all the different acronyms, but basically I have some sense of how it works, so I think it's not going to be so hard. But what date did we have it set for?

MR. BERMAN: You just had a month. You didn't give us a date for the November trial.

THE CLERK: Yes. It's November 6.

MR. EDWARDS: Originally, your Honor, you had November 8 as a potential trial date for BMS when we were doing Class 1 trials first.

MR. MONTGOMERY: But in your recent order, you simply said "in November."

THE COURT: All right, so fair enough. Okay, so

it's November 6? Okay. So I think that's right. As soon as I took Mr. Wise out of the hot seat as the only guy up there, never did I see a happier man as he walked out of the last hearing. Hopefully you're going to have to prove against separate defendants, so it is a bigger case.

MR. MONTGOMERY: You know, another issue I just would like to mention, if your Honor is going to do a proceeding that focuses on the defendants' conduct, it is important, I think, you understand that that same evidence is then going to be presented in the individual company cases on Class 1 beginning in March.

THE COURT: A lot of it will be.

MR. MONTGOMERY: It will be exactly the same evidence, so there is some inefficiency.

THE COURT: There's overlap, I understand that, but I just can't wait, and then something else will happen, and then something else will happen. I need some forward momentum on this case. As far as I was concerned, September was where I had blocked off huge amounts of time and staffed up and was ready to go, and then this issue happened with Medicare and with the plaintiffs assuming I'd go publication. That could happen again with another issue. What if the Medicare machines break down or there's another hurricane and then we get bumped again? Things happen that I can't control. But I can control 93A and my schedule, your

schedules, short of a national emergency, so I plan on doing this.

Now, to the extent I do this, does the United States want to be part of this?

MR. GOBENA: Your Honor, we've only intervened, obviously, against Abbott labs and Hospira, so I don't believe they're one of the defendants in that.

THE COURT: No, but I sure could use some amicus help on some of these issues.

MR. GOBENA: If your Honor would like that, we'd be more than happy to provide amicus briefing on any issues that your Honor would like.

THE COURT: So that's a good thought. On individual -- what's coming up obviously, is, will people from the Center for Medicare and Medicaid Services be subpoenaed as part of the trial?

MR. EDWARDS: No.

MR. BERMAN: Not from us.

MR. MONTGOMERY: We don't know.

THE COURT: Okay. So one thing, you could work together with them so -- Toohy regulations, is that it? Is that the name of those regulations that you don't get anyone unless you jump through three hurdles --

MR. HENDERSON: That's the name of it.

THE COURT: -- and do a backward flip, right? You

have to decide sooner rather than later if you want a government witness. The issue that might be worthwhile, which I cannot rule on motions for summary judgment till class notice goes out, a problem, at least for -- so, as I understand it, the motions for summary judgment are just sitting there on what AWP means, if you would like to submit an amicus as a statutory matter.

MR. GOBENA: You're asking the United States, your Honor?

THE COURT: Yes.

MR. GOBENA: Yes, I mean, if your Honor would like that, we can do that.

THE COURT: Thank you. So do I need my own expert? You all know this case at this point better than I do. Is there anything that's going to be so hard -- the one thing I'm worrying about is not the basic case; I think I can understand it as well as the next person. It's assessing the Daubert challenge. We've let go our independent expert, and the question is, on the expectation theory, which is a novel one, and I understand it's derived from the antitrust area, should I get somebody?

MR. MONTGOMERY: Your Honor, if you think it would be helpful, we certainly wouldn't disagree that it may. And while we let Professor Byrne go, I think there's still the reservation that you have to ask him if he's available again.

THE COURT: I talked with him, and I'm just trying to remember. I think he had a few offers to do things with the industry, and it was going to conflict him out.

MR. CAVANAUGH: Your Honor, we took an informal poll. We don't think any of the companies have retained him at this point.

THE COURT: I could give him a call.

MR. BERMAN: We were asked, if you recall, to stop retaining him because he wanted to go work for the industry.

THE COURT: But maybe he never did, but I think he had an -- I can't remember what it was. I think -- you know, it's funny, you think you remember and you don't -- I think he had an opportunity to go work with somebody in the industry, and he wasn't going to take it if I definitely needed him, and I told him at that stage I wasn't sure.

MR. BERMAN: But our concern is that it may not be these four but it may be three others in the AWP case that --

THE COURT: Well, I'll ask. I'll ask. And if not, I'll try and find somebody else. Do you have somebody else that you all agreed upon? Was there a runner-up when we put him in the saddle?

MR. CAVANAUGH: No.

MR. MONTGOMERY: No. They suggested Professor Byrne, and we accepted.

MR. SOBOL: Can we have a moment, your Honor?

THE COURT: Yes.

(Discussion off the record amongst plaintiffs' counsel.)

MR. SOBOL: The concern, your Honor, that the plaintiffs would have regarding either Professor Byrne or some other independent expert before you would be a vehicle by which any of the parties could at least question the expert if the expert was going down a trail which they, frankly, thought was incorrect.

THE COURT: I think that's actually helpful.

MR. SOBOL: And that would be an important procedural safeguard to make sure that --

THE COURT: So we're at the trial stage, not the class cert stage.

MR. SOBOL: Sure.

THE COURT: I think that's totally fair, I agree. Yes, that makes sense because even somebody who's neutral, I mean, it's a difference of expert opinion. It would highlight, at least, the fair areas of disagreement. So if he can't do it, I have actually one other person partly in mind, although I haven't asked him so I'm reluctant to float --

MR. CAVANAUGH: Don't tell us.

THE COURT: -- that I might call, and if he's available, then float the name, but I'll start with

Professor Byrne.

Okay, so proposed findings of fact and law, I don't think I need a pretrial memo. I don't have the room for all the memos that I've received in my office, so I think what we're better off doing is a brief set of proposed findings of fact and law just to give me a heads-up about where you're going, and then it can be supplemented afterwards. Does that make some sense to all of you? I'm talking about, you know, 20, 25 pages for proposed findings. We could do it the way, actually, you've done it in the past; maybe 25 pages sort of on any common industrywide issues and maybe -- does it make sense to do 15 for each company? I'm going to be getting very company-specific. I mean, at this point, I have to be quite candid, I haven't so much except for maybe a drug here or a drug there, and I'm assuming that it's going to have to be very specific per company.

MR. CAVANAUGH: It will be.

MR. MONTGOMERY: I think that would be easy for all of us to do, your Honor. I mean, we do have summary judgment papers in front of you. If it's more efficient for you to see this shorter form --

THE COURT: Would that be -- I mean, my concern is, as soon as I wait until after the trial to get proposed findings of fact, you will all ask for a month.

MR. MONTGOMERY: We're fine --

THE COURT: And then you ask for a continuance.

MR. MONTGOMERY: We're fine submitting proposed findings beforehand. I'm just reminding your Honor that there are summary judgment papers which --

THE COURT: Do you all want to rely on that? That makes sense.

MR. BERMAN: No. We would like to submit proposed findings.

THE COURT: Well, here's the issue with doing it afterwards: I forget, the problem is. I'm on to seventeen other things. I've got, believe it or not, two other MDLs. I've got a lot of criminal cases. So I'll forget. So when you ask for a month, and then you'll ask for a month continuance, and then you want to reply to one another, and now by the time I get to it, it's four or five months out, and I've forgotten. So I think we're really much better off with things in advance. And if you think the summary judgment motions, I can use that, that would be great.

MR. BERMAN: We need to first put in findings that focus more on the 93A issues and all our evidence related to that than we did in the summary judgment.

THE COURT: All right, fair enough. Really just so you don't all have to coordinate, do you want to each do a 20-page memo, that's it? I'll let you supplement afterwards, 20 pages of proposed findings of fact per

defendant, because it's going to be very defendant-specific, and --

MR. MONTGOMERY: Do you want common?

THE COURT: If you do. Otherwise I could just rely on the summary judgment. The common stuff, I think I know what you're going to say. Whether you prove it up, I don't know, but I think I know the case.

MR. MONTGOMERY: When would you like it?

THE COURT: I don't know. How about a week beforehand? Does that seem fair enough?

MR. CAVANAUGH: That's fine.

THE COURT: And you just told me this, but when was the opt-out time for the third-party payors?

MR. NOTARGIACOMO: October 1, your Honor.

THE COURT: So if I were to rule on the motion for summary judgment, it would probably have to be sometime in October, if I did. I may just move it all into the bench trial, depending on how it goes.

Is that all we need to deal with?

MR. BERMAN: Could I just ask -- and maybe everyone in Boston knows this, but I don't -- what days of the week you're going to hold court and the what the times will be?

THE COURT: In general, we go from 9:00 to 1:00 with a half an hour break at 11:00.

MR. EDWARDS: Five days?

THE COURT: Five days a week.

MR. EDWARDS: Your Honor, I assume we're going to have some exchange of witness lists and exhibits?

THE COURT: Yes, we'll send out a little pretrial order in general, yes, and premarked exhibits, and I'll want a set of exhibits for me and a set of exhibits for my law clerks. And I will guarantee you that if you start giving me 18 boxes a side, I won't look at it. I won't look at anything that's not flagged for me at the trial so I can put a sticky on it and underline it because I'm just not going to sit and read huge boxes of documents. So it would be very useful to have them here, and you'll turn me to such and such a page, and I will underline it, asterisk it and put a flag on it. But I'm not going to just sit and randomly read exhibits. It's not worth it just for an appellate record.

So, you know, we can just do it right now. A week beforehand you'll get me -- is that acceptable for a witness list, or do you want to know it further in advance than that? Two weeks in advance?

MR. EDWARDS: Yes, I would think further in advance, your Honor, so we can prepare for cross-examination.

THE COURT: All right, on both sides. So two weeks in advance, witness lists, premarked exhibits, and share them with one another; any motions in limine, although with a bench trial, I'll tend to just go as we go. And the key

unanswered question, absolutely essential, is: Do you agree that we should do 2 and 3 at the same time?

MR. BERMAN: No. We think, given the breadth of the evidence that you're going to hear in 2, we have to prove our case against each person, defendant, we should just get one clean shot done; and that by doing 2, we're going to have laid a foundation for 1 and 3 later on.

THE COURT: So what is the increment -- other than -- damages is obviously key, that whole expectation theory, but other than that, what would be different?

MR. BERMAN: Testimony about how people were looking at AWP used in the non-Medicare context. There's that whole other umbrella of, you know, they're going to say there were negotiations; we're going to say there were no negotiations. They're going to say physicians had market power to change it; we're going to say that they didn't. None of that is in Class 2 because they had to pay per statute.

THE COURT: Well, what if we were to just make it in a Class 2, but I would take everything from Class 2? In other words, I wouldn't start again from scratch.

MR. BERMAN: That would be fine with us as well.

THE COURT: And we could set something maybe in January -- well, we may all be dead by then, this is such a huge effort. And you'll get me if you think I should do it

all at once, and then maybe you'd explain why you think it's appropriate within the next week or two? Does that make sense, a couple of weeks? And you'll tell me why it isn't, and then we'll have plenty of time to resolve it.

MR. MONTGOMERY: Thank you.

THE COURT: But if we move beyond that, even if I only do 2, I would be planning on doing 3 pretty fast right afterwards. And also, if you could give me some really fair sense of how long you think it would take and the difference between 2 and 3, would it make a difference, that would be really useful.

MR. EDWARDS: Your Honor, at the risk of belaboring the issue, would it make sense for plaintiffs to provide witness lists and exhibit lists first so that we're not passing like ships in the night if we do it simultaneously?

MR. BERMAN: It should be mutual, your Honor. We have a lot of work to do, and to make us give it to them earlier is a lot.

THE COURT: But it does make some sense. So three weeks in advance of the trial you do it. Two weeks in advance of the trial you do it, and then you can supplement, as long as --

MR. BERMAN: That's fair.

THE COURT: Okay, to meet head on what they're going to do, okay? And then my --

MR. SOBOL: Witnesses and exhibits, your Honor?

THE COURT: Yes. And my sense is, for people out of town, we're certainly not going to do it the Wednesday before Thanksgiving so you can get out of here by Tuesday, and I'll stop the week before Christmas so people can be home for Christmas parties and the like. So I've got to assume we're going to be done before Christmas. At least I'll be very reluctant to have a trial go beyond that, let's put it that way. So that would leave us what, six weeks? This is probably only going to be a month anyway. I doubt I'm going to let it go a full six weeks. So are we all set?

MR. DALY: Your Honor, I wanted to address the amicus point that your Honor raised, speaking for Abbott and Hospira. The federal government, the Department of Justice, CMS, they are now in this case. They are advocates, they are litigants. And Abbott, for one, would object to an amicus brief being filed by an advocate in a matter that's before your Honor. For example, we have a motion to dismiss that's pending that your Honor will be looking at in due course, and we would object to the United States being treated as an amicus on issues that will be litigated in this case with them as a party.

THE COURT: I understand, but a lot of the -- and I will take it with that weight that they're now in it. That having been said, it's a statutory issue and they're the

agency. I'm assuming they're going to represent CMS in this, right?

MR. GOBENA: They're our client, your Honor.

THE COURT: They're your client? So I would like to know what CMS's position is.

MR. GOBENA: Your Honor, a procedural matter related to that. When would you like any briefing on this issue? I mean, I understand you have a trial coming up.

THE COURT: I'm not here to destroy your family vacation. When could you do it?

MR. GOBENA: You know, I think I'd probably need a few weeks.

THE COURT: You're getting a whisper from over here.

MR. GOBENA: Your Honor, if we could have it by September 15, the second week in September, if everything's provided, that would be helpful for us.

THE COURT: September 15.

MR. GOBENA: Is that too late for your Honor?

THE COURT: Okay. But it can't be an extension because the truth is, if I'm going to rule on it, the motion for summary judgment, I can't rule on it until after the opt-out period, which is only two weeks later. However, the trial is looming. I'm not sure I can get out a decision -- I may merge it all into the bench trial, but it can't be any

later than that. So I know you have a thousand hoops to jump through down there, but I'll need it.

And let me ask you this: If they need some witness from the Center for Medi -- either side decides to call someone, are you the person they should get in touch with to sort of jump any of those hurdles?

MR. GOBENA: Either contact myself or AUSA Henderson.

MR. DeMARCO: Your Honor, on behalf of the Track 2s --

THE COURT: Yes, I saw you sitting back there silently.

MR. DeMARCO: Thank you. Good afternoon, your Honor.

THE COURT: Good afternoon. Welcome back.

MR. DeMARCO: If the Track ls are finished, we just wanted to have a few minutes to address a couple of lingering Track 2 issues, in light of the upcoming class cert hearing next month.

THE COURT: Okay. I haven't read it yet.

MR. DeMARCO: That's fine. We don't want to cut into their time.

THE COURT: No, they're done.

MR. DeMARCO: They're done. Okay, well, my colleague Scott Stempel would like to raise a couple of

issues with respect to the class cert hearing and a couple of other housekeeping matters as well.

MR. STEMPELL: Your Honor, just one issue with respect to the class cert hearing that occurs. As you were discussing the possibility of bringing in an independent expert, we thought it was a terrific area when you did it to consider class certification for Track 1. We've got the hearing coming up. Professor Byrne specifically identified some areas that were in need of further development of the record, which is exactly where we focused in discovery when you sent us off to do discovery; specifically, the treatment of multisource drugs and private payor physician-administered drugs. And we think it would be helpful to have an independent expert, Professor Byrne if he's available, consider the record that we've developed to shed some light on any lingering questions.

THE COURT: On class cert?

MR. STEMPELL: On class cert, in continuation of the role he has played, and in fact --

THE COURT: I'll see. I released him, so I just would have to find out.

MR. STEMPELL: There's one housekeeping issue that Abbott and Dey have asked me to raise, and that is an open issue on an objection from a ruling from Magistrate Bowler. It's Docket 2140. It was fully briefed back in March, and it

had to do with a --

THE COURT: The objections were briefed?

MR. STEMPELL: Yes, the objections were briefed. Judge Bowler issued an order quashing some third-party subpoenas and --

THE COURT: I'm sorry, I missed that, so I'm glad you brought that up, so we'll get those.

MR. STEMPELL: And just to alert you, we believe we have reached an agreement, and we'll be submitting a joint scheduling order relating to Mr. Bean, who is the belatedly added class rep.

THE COURT: Okay, thank you. And have we subpoenaed CMS yet for the lists with respect to Track 2 so I'm not back where I started?

MR. BERMAN: We're right on the verge.

MR. MONTGOMERY: Your Honor, with respect to the amicus brief, we would like leave to respond, if there's anything we need to respond to it.

THE COURT: Of course.

MR. MONTGOMERY: And in particular, we'd like to address the question, at least these three gentlemen would, whether it's appropriate for your Honor to rule on the statutory issue in light of the pendency of the notice process with respect to Class 1. I think there's a potential complication there as a Rule 23 matter.

THE COURT: Well, I can do it with respect to TPPs, and then I'm going to have to do it again with respect to Class 1. And that's a legal issue, in any event. What I'm trying to say is, the odds of my issuing an opinion before the -- what it might mean I have to do is wait until the opt-out period for Class 1.

MR. MONTGOMERY: And that's all I was suggesting.

THE COURT: But it doesn't mean I have to stop doing the trial.

MR. MONTGOMERY: I wasn't suggesting that, your Honor. It was just a matter of when you issue a ruling.

THE COURT: It's a good question because essentially, while not technically binding on the class, as a matter of law of the case -- I wouldn't be violating anything by doing that, but the question is whether it's wise. Do you follow me, Mr. Sobol and Mr. Berman?

MR. BERMAN: Yes, your Honor. And our position is that since you're not ruling on a claim but you're only ruling on the legal meaning of the term, that you can do that before the Class 2 trial, and that it's really not --

THE COURT: It may be. I just haven't thought of it, and it's a great point. I'll think of it. If worse comes to worse -- I mean, I'm not going to spit this thing out like a, my expression, an ATM ruling where you stick in the card and out comes the opinion. The odds of my even

finishing it before the opt-out period for the Class 1s is pretty low, I think, so -- okay, great, have a nice summer, because I don't see you again, do I?

MR. BERMAN: No, your Honor.

THE CLERK: Court is in recess.

C E R T I F I C A T E

UNITED STATES DISTRICT COURT)
DISTRICT OF MASSACHUSETTS) ss.
CITY OF BOSTON)

I, Lee A. Marzilli, Official Federal Court Reporter, do hereby certify that the foregoing transcript, Pages 1 through 35 inclusive, was recorded by me stenographically at the time and place aforesaid in Civil Action No. 01-12257-PBS, MDL No. 1456, In re: Pharmaceutical Industry Average Wholesale Price Litigation, and thereafter by me reduced to typewriting and is a true and accurate record of the proceedings.

In witness whereof I have hereunto set my hand this 8th day of August, 2006.

LEE A. MARZILLI, CRR
OFFICIAL FEDERAL COURT REPORTER

Exhibit B

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF ADMINISTRATION
WASHINGTON, D.C. 20503

October 25, 2006

Mr. John T. Montgomery
Ropes & Gray LLP
One International Place
Boston, MA 02110-2624

Re: *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, D. Mass. Civil Action No. 01-12257-PBS, Judge Patti B. Saris

Dear Mr. Montgomery:

On October 23, 2006, I received your letter dated October 17, 2006, in which you requested the Office of Administration, Executive Office of the President, approve the testimony of Mr. Christopher C. Jennings, former Deputy Assistant to the President for Health Policy Development, who completed his service in that capacity at the close of the last Presidential Administration in 2001. You made your request in accordance with 5 C.F.R. § 2502.30, *et seq.*

Please be advised that 5 C.F.R. § 2502.30, *et seq.*, applies only to the Office of Administration. Specifically, 5 C.F.R. § 2502.31 pertains to an "employee or former employee of the Office of Administration..." Because Mr. Jennings was not an employee of the Office of Administration, this office is not in a position to act on your request.

Sincerely,

Victor E. Bernson, Jr.
General Counsel

Exhibit C

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re. PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Hon. Patti Saris
THIS DOCUMENT RELATES TO THE AMENDED MASTER CONSOLIDATED CLASS ACTION	

MOTION OF UNITED STATES TO BE ADDED AS AN INTERESTED PARTY

The United States of America, through its undersigned counsel, hereby moves this Court to be added as an "interested party" in the electronic case filing system applicable to this action. In support of this motion, the United States states that during the course of this litigation it has filed an amicus brief and several papers relating to subpoenas issued to the Department of Health and Human Services (DHHS) and to a DHHS contractor. The Court has recently asked the United States, on behalf of the DHHS, to file a statement regarding the possible use of a mass mailing by the Centers for Medicare & Medicaid Services to Medicare beneficiaries. Under the Court's ECF system, any electronic filing must be made on behalf of an entity identified as a participant in the ECF case system for the case. The United States asks that it be added as an "interested party" so that it can electronically file papers on its own behalf.

Wherefore, in order to facilitate electronic filings, the United States requests that it be added as an "interested party" in the electronic case filing system for this action.

Respectfully submitted,

MICHAEL J. SULLIVAN
United States Attorney

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Dated: July 20, 2006